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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,823	12/08/2003	Robert C. Getts	4081.009.210	7558

7590 09/27/2006
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,823	GETTS, ROBERT C.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1-5 are currently pending and are examined in the office action.

Priority

2. This application filed on December 8, 2003 is a CON of 10/393,519 filed on 3/20/03 ABN, which is a CON of PCT/US01/29589 filed on 2001, which claims benefit of US provisional 60/234,060 filed on 9/20/2000, and this application is a CIP of 09/802,162 filed on 3/8/2001 which claims benefit of 60/187,681 filed on 3/8/2000 and a CIP of 09/908,950 filed on 7/19/2001 which claims benefit of 60/219,397 filed on 7/19/2000.

Drawings

3. The drawings are objected to because the Fig.3 filed on 5/28/2004 represents informal drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Objection to the Specification

4. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Figure 3 which recites a poly(A) and Poly(T) sequences having more than 10 nucleotides) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). For clarity purposes Applicant is required to represent each sequence by a SEQ ID No.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4 recite the limitation "said fragment" in line 1 of step b) of the claims. There is insufficient antecedent basis for this limitation in the claim. The limitation "said fragment" lacks support because the preceding step does not recite a fragment. Thus the limitation makes

the claims unclear because it is not clear whether the recited limitation refers to a fragment of the linearized vector or does it refer to the linearized vector itself. Amendment to recite 'said linearized vector' would obviate the rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinshilboum et al. (US 5,744, 355) in view of Nilsen et al. (USPN. 5, 487,973).

Weinshilboum et al. teach a method claim 1, 4 for detecting nucleic acids, wherein the method comprises

(a) linearizing a vector containing vector nucleic acid (pBluescript) and a cloned nucleic acid (EST cDNA) (see col. 18, line 43-45, col. 20, line 25-32, col. 26, line 62-64).

(b) transcribing said linearized vector fragment to produce a transcribed nucleic acid comprising a segment derived from said vector and a segment derived from said cloned nucleic acid, said segment derived from said vector comprises a capture sequence and said cloned nucleic acid comprises a probe (EST cDNA used as a probe) (see col. 18, line 43-45, col. 20, line 25-32, col. 26, line 62-64).

(d) providing a membrane comprising target nucleic acid (northern or southern blot) (see col. 26, line 62-67, col. 27, line 1-19);

(e) conducting a blot assay or hybridization using said transcribed nucleic acid as probe and said membrane bound target (see col. 26, line 62-67, col. 27, line 1-19, col. 28, line 1-10).

With regard to claim 2, Weinshilboum et al. teach that the method further comprises fixing genomic DNA to said membrane (nylon membrane) (see col. 27, line 13-19).

However, Weinshilboum et al. did not teach providing dendrimer molecules comprising a complementary sequence to said capture sequence and a signal sequence.

Nilsen et al. teach a method of claims 1-5, for detecting a specific nucleic acid in a target sample using a dendrimeric probe wherein Nilsen et al. teach that the method comprises (i) contacting a bead having specific probe sequences with a mixture containing a first component comprising labeled target nucleic acid (DNA or RNA) having a capture sequence and a second component comprising a dendrimer having at least one arm with a nucleotide sequence complementary to the capture sequence of the first component (see column 14, lines 30-35, column 15, lines 37-63); (ii) mixing the first and second components at a temperature to form a bridge between the two components to enable the cross-linking of first component to the second (see column 16, lines 8-11); and incubating the bound mixture with the said bead and detecting signal as an indication of the binding of the target sequence to the specific probe sequence on the bead (see column 16, lines 12-67, column 18, lines 27-51).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method as taught by Weinshilboum et al. with a method for detecting a nucleic acid sequence using dendrimer as taught by Nilsen et al. to achieve expected advantage of developing an enhanced sensitivity of detecting a target nucleic acid because Nilsen et al. states that "background noise could be generated in conventional assay

not only from binding to a solid support, but also from binding of the probe to nonhomologous DNA sequences. An open branching of a dendrimeric DNA have many degrees of freedom in their movement relative to each other and have a high avidity for DNA that is complementary to the non-annealed single stranded sequences (see column 18, lines 14-26, column 7, lines 14-19). An ordinary practitioner would have been motivated to combine the method of Weinshilboum et al. with the step of adding dendrimeric probe as taught by Nilsen et al. in order to achieve the expected advantage of developing a sensitive method for detecting a target nucleic acid because the ordinary practitioner would have a reasonable expectation of success that inclusion of said dendrimer molecules would result in the reduction of non-specific binding that would reduce background noise and enhance specific hybridization signal and such modification of the method is considered obvious over the cited prior art in the absence of secondary considerations.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637


SURYAPRABHA CHUNDURU
PATENT EXAMINER